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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,106	01/29/2004	Joel E. Bernstein	DUS100/4-SUS	4430

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VINSON & ELKINS, L.L.P.
1001 FANNIN STREET
2300 FIRST CITY TOWER
HOUSTON, TX 77002-6760

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/767,106	Applicant(s) BERNSTEIN, JOEL E.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-12 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to a method of treating acne comprising administering a composition comprising nicotinamide and nicotinic acid, classified in class 424, subclass 401.
- II. Claims 7-12, drawn to a topical carrier comprising nicotinamide and nicotinic acid, classified in class 424, subclass 70.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the topical composition comprising nicotinamide and nicotinic acid can be used in a materially different process such as hair treatment compositions for hair growth.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

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Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Attorney Fleming on November 2006 a provisional election was made with traverse to prosecute the invention of I, claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-12 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 and 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (4,505,896).

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Bernstein teaches a method of treating acne vulgaris comprising application of an “effective amount of nicotinic acid or nicotinamide or a combination thereof” with sulfur, salicylic acid, benzoyl peroxide, erythromycin, clindamycin or vitamin A. see column 1, lines 60-68. Bernstein teaches the use of nicotinic acid and nicotinamide in an amount from 1 to 10%. See column 2, lines 10-25. Example 9 teaches the use of 1%, 5%, or 10% of nicotinic acid and nicotinamide.

Bernstein does not exemplify a composition comprising nicotinic acid and nicotinamide; however it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Bernstein and utilize a composition comprising nicotinic acid and nicotinamide to treat acne. One would have been motivated to do so with a reasonable expectation of success since Bernstein suggests the combination of nicotinic acid and nicotinamide. Therefore, the combination of nicotinic acid and nicotinamide to treat acne is prima facie obvious in view of Bernstein’s teachings.

With regard to the claimed range of “less than 1%” in claim 1 and 0.005-0.7% in claim 3, Bernstein teaches the use of nicotinic acid in an amount of 1%, the manipulation of this concentration is considered obvious absent the unexpectedness of the instantly claimed amount. With regard to claim 3, “0.7%” is considered to be obvious over Bernstein’s teaching of 1% absent the showing of the unexpectedness of 0.7% versus 1%. “Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to

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discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein (4,505,896) in view of Scivoletto (6,248,763).

The teaching of Bernstein have been set forth above.

Bernstein does not teach 0.05-0.2% nicotinic acid.

Scivoletto teaches a composition comprising nicotinic acid, nicotinamide, and nicotinic esters as the active ingredient to treat skin disorders including acne. See abstract. Scivoletto teaches the use of nicotinic acid in the amount of 0.01-1%. See examples.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bernstein and Scivoletto and utilize the instant nicotinic acid concentration. One would have been motivated to do so since Scivoletto teaches the nicotinic acid for the treatment of acne in the amount of 0.01-1%. Scivoletto teaches the same compound in the instant range for the same purpose. Thus, it is prima facie obvious to utilize the instant range since the prior art teaches the effective range of nicotinic acid for the same purpose.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scivoletto et al (6,429,218) in view of Bernstein (4,505,896).

Scivoletto teaches a composition for reducing enlarged pores, minimizing fine lines, penetration of moisturizer ingredients, shrinking of pimples, removal of blackheads and other unwanted dirt under the skin comprising niacin (nicotinic acid). See column 1, lines 39-45 and column 2, lines 15-20. The examples teach a composition comprising 0.01-2.5% methyl nicotinate and 0.01-2.5% nicotinic acid, among other ingredients. See column 3. Scivoletto

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teaches the addition of 0.01-3% nicotinic acid and nicotinic acid amides (nicotinamide) in the amount of 0.01-20% to the "base formula" to increase the flushing and reddening provided by the composition. Scivoletto teaches for acne other active agents such as salicylic acid may be used. See column 4, lines 10-16.

Although Scivoletto teaches the method of shrinking pimples, Scivoletto does not specifically teach the treatment of acne vulgaris.

Bernstein teaches a method of treating acne vulgaris comprising application of an effective amount of nicotinic acid or nicotinamide. See abstract. Bernstein teaches the use of nicotinic acid and nicotinamide in an amount from 1 to 10%. See column 2, lines 10-25.

Example 9 teaches the use of 1%, 5%, or 10% of nicotinic acid and nicotinamide.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Scivoletto and Bernstein and utilize Scivoletto's composition to specifically treat acne vulgaris. One would have been motivated to do so since Bernstein teaches nicotinamide and nicotinic acid are effective in treating acne vulgaris. Further, a skilled artisan would have reasonably expected success since Scivoletto teaches the composition is effective in shrinking pimples, a symptom of acne, and active ingredients for treating skin disorders such as acne may also be utilized.

With regard to claim 5-6, Scivoletto suggests further utilizing active agents such as salicylic acid in the nicotinic acid and nicotinic acid amide composition.

Conclusion

Claims 1-6 are rejected. Claims 7-12 are withdrawn as being directed to a non-elected invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sharmila S. Gollamudi
Examiner
Art Unit 1616